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PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

7

Application Number

10/678,212

Filing Date

October 2, 2003

First Named Inventor

Hawley, Michael

Art Unit

1614

Examiner Name

Unknown

Attorney Docket Number

6794S-000028/US/01

ENCLOSURES (check all that apply)☐ Fee Transmittal Form☐ Fee Attached☐ Amendment / Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure
Statement☐ Certified Copy of Priority
Document(s)☐ Reply to Missing Parts/
Incomplete Application☐ Reply to Missing Parts
under 37 CFR1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a
Provisional Application☐ Power of Attorney, Revocation
Change of Correspondence Address☐ Terminal Disclaimer☐ Request for Refund☐ CD, Number of CD(s) _____☐ Landscape Table on CD☐ After Allowance Communication to TC☐ Appeal Communication to Board
of Appeals and Interferences☐ Appeal Communication to TC
(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☐ Other Enclosure(s)
(please identify below):Information Disclosure Statement
Form 1449

References (6)

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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm

Harness, Dickey & Pierce, P.L.C.

Signature

Printed Name

David M. Gryte

Date

JULY 15, 2005

Reg. No.

41,809

CERTIFICATE OF TRANSMISSION/MAILING

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EV 726254284 US

Signature

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JULY 15, 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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EV-726254284 US



THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Michael Hawley, *et al.*
Serial No: 10/678,212
Filed: October 2, 2003
For: Compositions and Methods for Treating Sexual Dysfunction
Confirmation No: 2159
Group Art Unit: 1625
Examiner: Evelyn Mei Huang
Pharmacia Ref: 0527/US
Pfizer Ref: 24964A/US
HDP Ref: 6794S-000028/US/01

July 15, 2005

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam/Sir:

To comply with 37 CFR §1.97 and §1.98, Applicants submit the enclosed Form PTO-1449.

In accordance with MPEP §609 and §707.05(b), Applicants respectfully request that each document listed be given thorough consideration, and that the Examiner cite each document of record in the prosecution history of the present application by initialing the Form PTO-1449 next to each document. Applicants request such initialing even if the Examiner does not consider: (1) a document to be sufficiently pertinent to use in a rejection; (2) a document to be prior art for any reason; or (3) that the guidelines for citation have been fully complied with respecting a particular document. Applicants make this request so that each document becomes cited on the face of a patent issuing on the present application.

Applicants submit this information disclosure statement in compliance with the duty to disclose information material to patentability under 37 CFR §1.56, but by listing such documents are not admitting that such documents are necessarily relevant or prior art. Applicants intend no representation that the listed documents represent the results of a complete search. Applicants

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Information Disclosure Statement
Appl. No. 10/678,212
July 15, 2005

anticipate that the Examiner, in the normal course of examination, will make an independent search consistent with 37 CFR §1.104(a), and, in the course of such search, will review for relevance every document listed on the attached form even if not initialed.

Most references cited in this information disclosure statement are U.S. patents or U.S. patent application publications. Copies of those references are therefore not being provided in accordance with 37 C.F.R. §1.98(d) and MPEP §609 Part III(A)(2). Applicants, however, will provide copies of such references upon request from the Examiner.

Applicants make no representation as to the accuracy of any translation provided with this Information Disclosure Statement.

Applicants request early and favorable consideration.

* * * * *

No Office action has issued in this application as of this date. Accordingly, this information disclosure statement is being filed pursuant to 37 C.F.R. §1.97(b)(3). Applicants do not believe that they owe any fee in connection with this filing. If, however, Applicants do owe any such fee(s), the Commissioner is hereby authorized to charge such fee(s) to Deposit Account No. **08-0750**. In addition, if there is ever any other fee deficiency or overpayment under 37 C.F.R. §1.16 or §1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **08-0750**.

The Examiner is requested to call the undersigned if any questions arise that can be addressed over the phone to expedite examination of this application.

Respectfully submitted,



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Information Disclosure Statement
Appl. No. 10/678,212
July 15, 2005

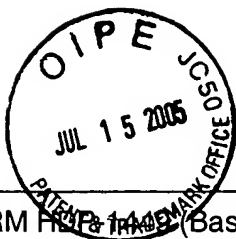


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A handwritten signature in black ink, appearing to read "David A. [unclear]", written over a horizontal line.

DMG/PML
Enclosures



FORM PTO-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 3

ATTORNEY DOCKET NO.

6794S-00028/US/01

SERIAL NO.

10/678,212

APPLICANT

Hawley, et al

FILING DATE

October 2, 2003

GROUP

1614

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		3,885,026	05/20/1975	Heinemann et al.	424/14	
2.		4,134,943	01/16/1979	Knitsch et al.	264/28	
3.		4,305,502	12/15/1981	Gregory et al.	206/532	
4.		4,371,516	02/01/1983	Gregory et al.	424/22	
5.		4,414,198	11/08/1983	Michaelson	424/44	
6.		4,855,326	08/08/1989	Fuisz	514/777	
7.		4,946,684	08/07/1990	Blank et al.	424/441	
8.		5,073,374	12/17/1991	McCarty	424/435	
9.		5,082,667	01/21/1992	Van Scoik	424/469	
10.		5,178,878	01/12/1993	Wheling et al.	424/466	
11.		5,273,975	12/28/1993	Moon et al	514/233.2	
12.		5,298,261	03/29/1994	Pebley et al.	424/488	
13.		5,401,514	03/28/1995	Juch et al.	424/465	
14.		5,417,985	05/23/1995	Coutel et al.	424/489	
15.		5,464,632	11/07/1995	Cousin et al.	424/465	
16.		5,466,464	11/14/1995	Masaki et al.	424/434	
17.		5,501,861	03/26/1996	Makino et al.	424/464	
18.		5,503,846	04/02/1996	Wehling et al.	424/466	
19.		5,518,730	05/21/1996	Fuisz	424/426	
20.		5,576,014	11/19/1996	Mizumoto et al.	424/435	
21.		5,587,172	12/24/1996	Cherukuri et al.	424/401	

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 2 of 3	ATTORNEY DOCKET NO.	SERIAL No.
	6794S-000028/US/01	10/678,212
	APPLICANT	
	Hawley, et al.	
	FILING DATE	GROUP
	October 2, 2003	1614

U.S. PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
22.		5,587,180	12/24/1996	Allen, Jr. et al.	424/499	
23.		5,607,697	03/04/1997	Alkire et al.	424/495	
24.		5,622,719	04/22/1997	Myers et al.	424/488	
25.		5,652,245	07/29/1997	Romero	514/292	
26.		5,653,926	08/05/1997	Bogue et al.	264/120	
27.		5,662,849	09/02/1997	Bogue et al.	435/192	
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29.		5,762,961	06/09/1998	Roser et al.	424/464	
30.		5,807,576	09/15/1998	Allen, Jr. et al.	424/465	
31.		5,837,285	11/17/1998	Nakamichi et al.	424/464	
32.		5,869,098	02/09/1999	Misra et al.	424/484	
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34.		5,939,091	08/17/1999	Eoga et al.	424/441	
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36.		6,010,719	01/04/2000	Remon et al.	424/464	
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39.		6,448,258	09/10/2002	McCall et al.	514/292	
40.		6,455,564	09/24/2002	Meglasson et al.	514/387	
41.		6,586,595	07/01/2003	Wuts	546/64	

Examiner:	Date Considered:
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FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 3 of 3	ATTORNEY DOCKET NO.		SERIAL NO.
	6794S-000028/US/01		10/678,212
	APPLICANT		
	Hawley, et al.		
	FILING DATE	GROUP	
	October 2, 2003	1614	

U.S. PATENT DOCUMENTS						
Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
42.		6,602,868	08/05/2003	McBrinn et al.	514/224.2	

FOREIGN PATENT DOCUMENTS							
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes No	
43.		WO 99/16442	04/08/1999	PCT	A61K 31/47, 9/20		
44.		WO 00/40226	07/13/2000	PCT	A61K 31/00		
45.		WO 02/062315	08/15/2002	PCT	A61K 9/10		

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
46.		Chang, et al., <u>Fast-Dissolving Tablets</u> , <i>Pharmaceutical Technology</i> , pp. 52-58 (2000)
47.		Heier, et al., <u>Synthesis and Biological Activities of (R)-5,6-Dihydro-N,N-dimethyl-4H-imidazo[4,5,1-i] quinolin-5-amine and Its Metabolites</u> , <i>J. Med. Chem.</i> , 40(5):639-646 (1997)
48.		International Search Report (08.27.2004) and Written Opinion (05.09.2005) issued in International Application No. PCT/US03/31656

Examiner:	Date Considered:
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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.